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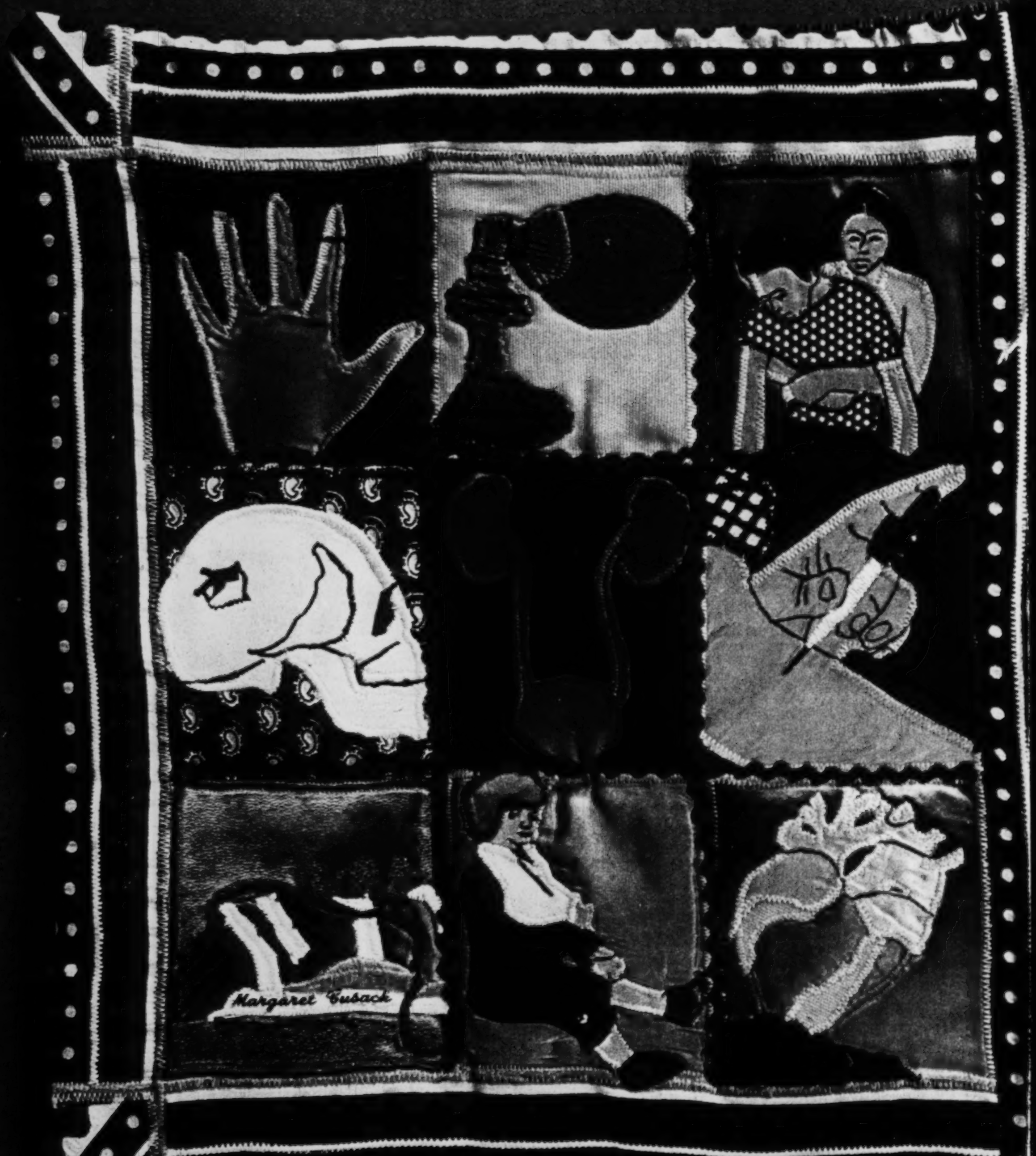
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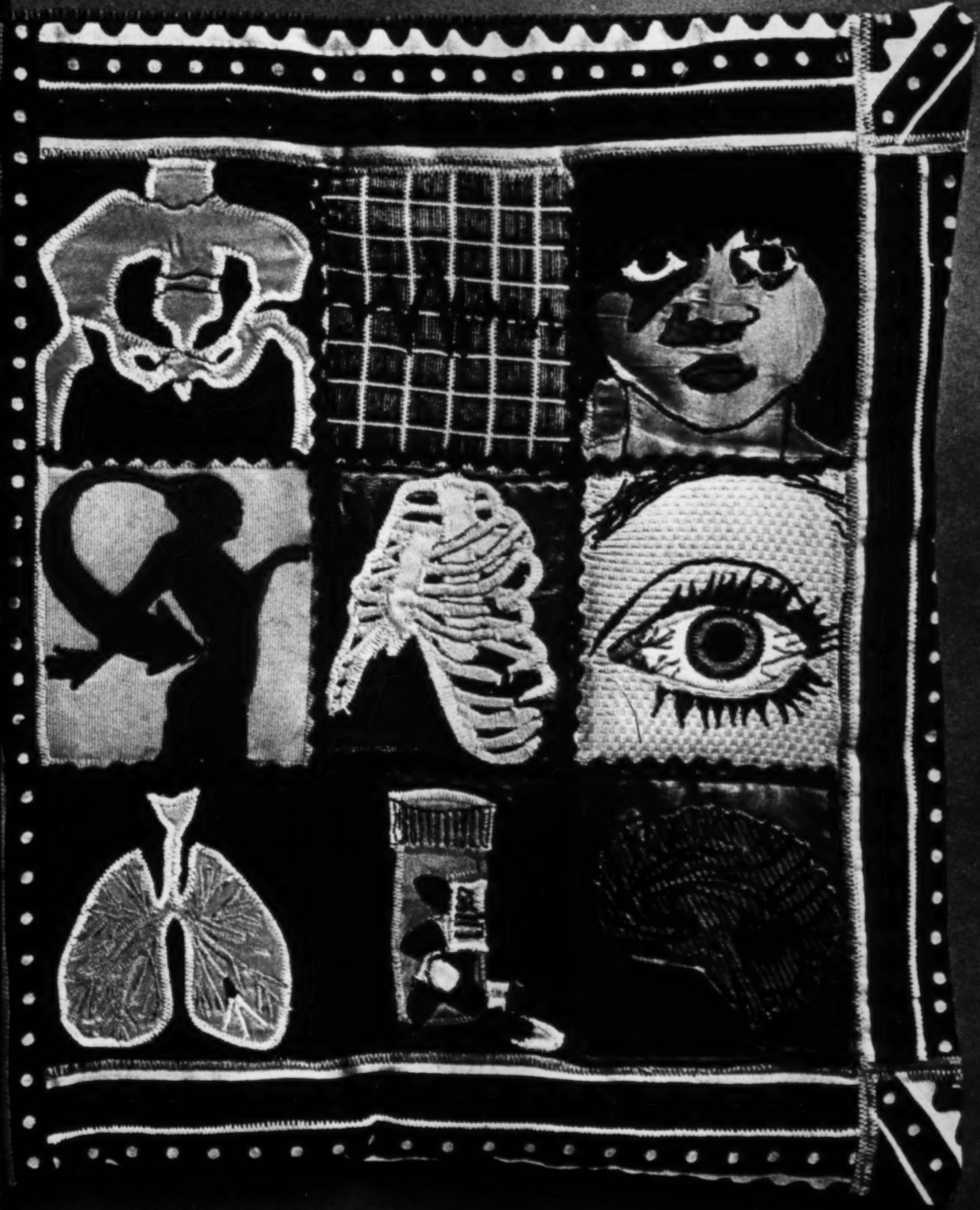
VOLUME 7



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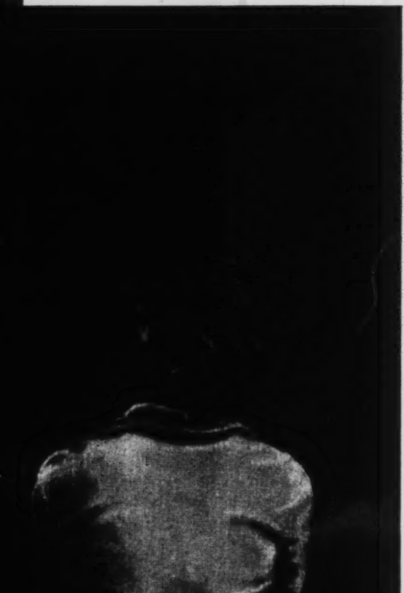

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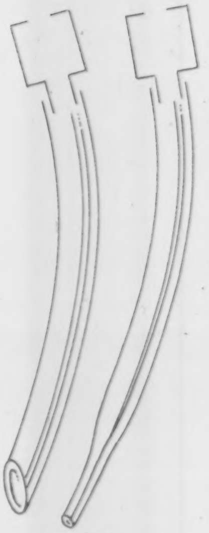
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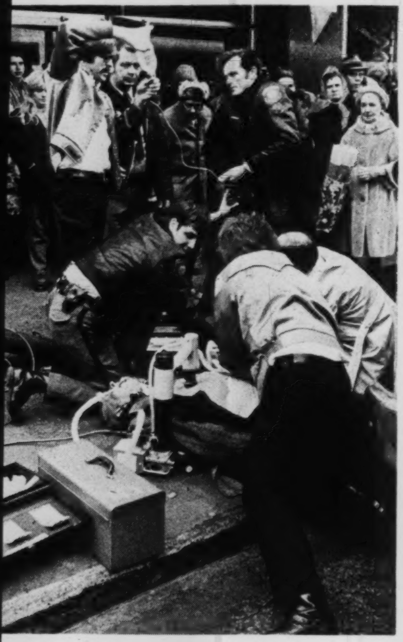

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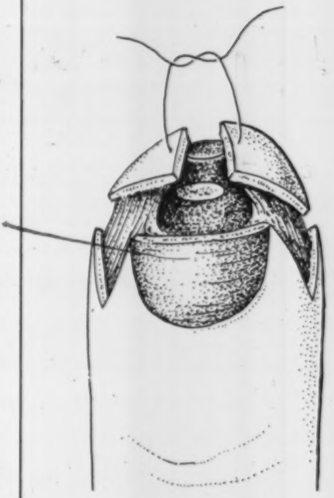

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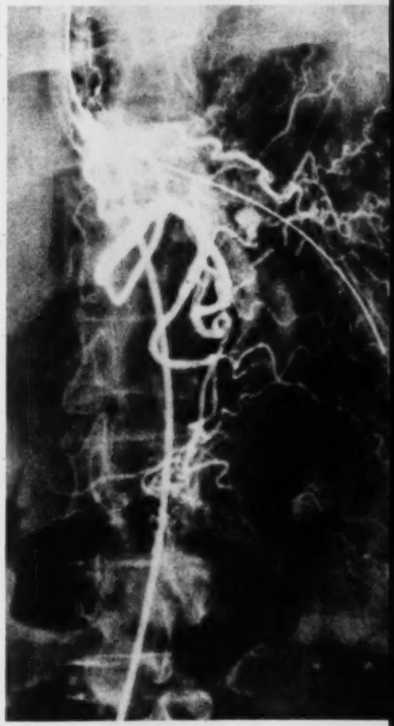

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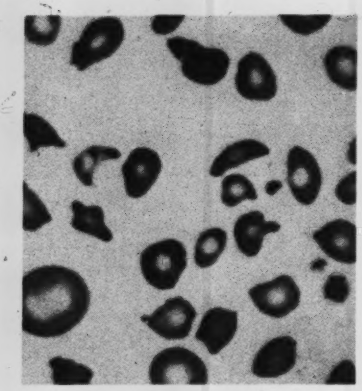
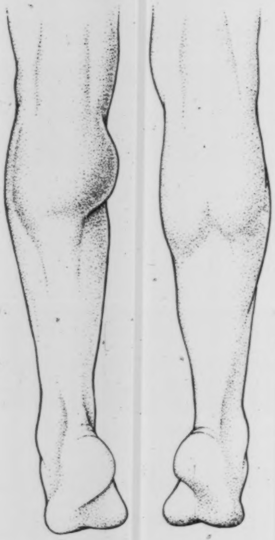


anemia



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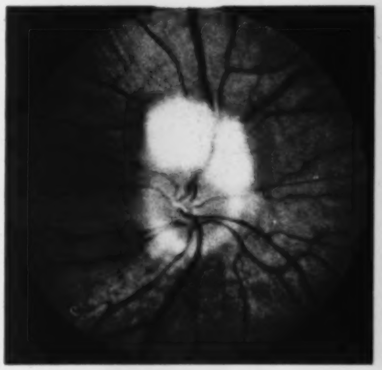

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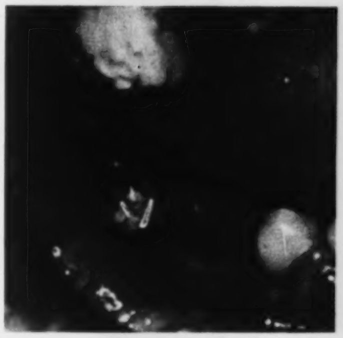

cancer

arrhythmia

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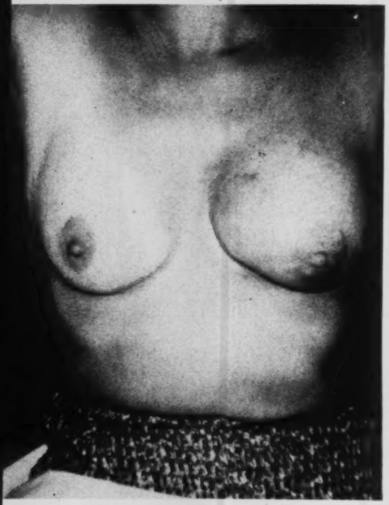
trick knee



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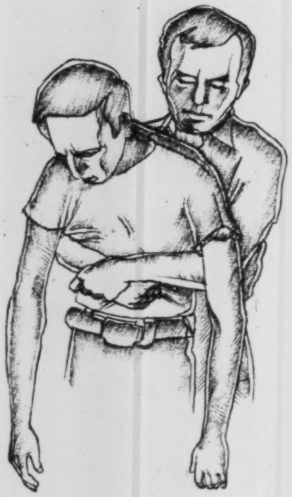

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diarrhea

Hodgkin's disease

***IMPORTANT INFORMATION:** This is a Schedule V substance by Federal law; diphenoxylate HCl is chemically related to meperidine. In case of overdosage or individual hypersensitivity, reactions similar to those after meperidine or morphine overdosage may occur; treatment is similar to that for meperidine or morphine intoxication (prolonged and careful monitoring). Respiratory depression may recur in spite of an initial response to Nalline® (nalorphine HCl) or Narcan® (naloxone HCl) or may be evidenced as late as 30 hours after ingestion. LOMOTIL IS NOT AN INNOCUOUS DRUG AND DOSAGE RECOMMENDATIONS SHOULD BE STRICTLY ADHERED TO, ESPECIALLY IN CHILDREN. THIS MEDICATION SHOULD BE KEPT OUT OF REACH OF CHILDREN.*

Indications: Lomotil is effective as adjunctive therapy in the management of diarrhea.

Contraindications: In children less than 2 years, due to the decreased safety margin in younger age groups, and in patients who are jaundiced or hypersensitive to diphenoxylate HCl or atropine.

Warnings: Use with special caution in young children, because of variable response, and with extreme caution in patients with cirrhosis and other advanced hepatic disease or abnormal liver function tests, because of possible hepatic coma. Diphenoxylate HCl may potentiate the action of barbiturates, tranquilizers and alcohol. In theory, the concurrent use with monoamine oxidase inhibitors could precipitate hypertensive crisis. In severe dehydration or electrolyte imbalance, withhold Lomotil until corrective therapy has been initiated.

Usage in pregnancy: Weigh the potential benefits against possible risks before using during pregnancy, lactation or in women of childbearing age. Diphenoxylate HCl and atropine are secreted in the breast milk of nursing mothers.

Precautions: Addiction (dependency) to diphenoxylate HCl is theoretically possible at high dosage. Do not exceed recommended dosages. Administer with caution to patients receiving addicting drugs or known to be addiction prone or having a history of drug abuse. The subtherapeutic amount of atropine is added to discourage deliberate overdosage; strictly observe contraindications, warnings and precautions for atropine; use with caution in children since signs of atropinism may occur even with the recommended dosage. Use with care in patients with acute ulcerative colitis and discontinue use if abdominal distention or other symptoms develop.

Adverse reactions: Atropine effects include dryness of skin and mucous membranes, flushing, hyperthermia, tachycardia and urinary retention. Other side effects with Lomotil include nausea, sedation, vomiting, swelling of the gums, abdominal discomfort, respiratory depression, numbness of the extremities, headache, dizziness, depression, malaise, drowsiness, coma, lethargy, anorexia, restlessness, euphoria, pruritus, angioneurotic edema, giant urticaria, paralytic ileus, and toxic megacolon.

Dosage and administration: ***Lomotil is contraindicated in children less than 2 years old.*** Use only Lomotil liquid for children 2 to 12 years old. For ages 2 to 5 years, 4 ml. (2 mg.) t.i.d.; 5 to 8 years, 4 ml. (2 mg.) q.i.d.; 8 to 12 years, 4 ml. (2 mg.) 5 times daily; adults, two tablets (5 mg.) t.i.d. to two tablets (5 mg.) q.i.d. or two regular teaspoonfuls (10 ml., 5 mg.) q.i.d. Maintenance dosage may be as low as one fourth of the initial dosage. Make downward dosage adjustment as soon as initial symptoms are controlled.

Overdosage: Keep the medication out of the reach of children since accidental overdosage may cause severe, even fatal, respiratory depression. Signs of overdosage include flushing, hyperthermia, tachycardia, lethargy or coma, hypotonic reflexes, nystagmus, pinpoint pupils and respiratory depression which may occur 12 to 30 hours after overdose. Evacuate stomach by lavage, establish a patent airway and, when necessary, assist respiration mechanically. A narcotic antagonist may be used in severe respiratory depression. Observation should extend over at least 48 hours.

Dosage forms: Tablets, 2.5 mg. of diphenoxylate HCl with 0.025 mg. of atropine sulfate. Liquid, 2.5 mg. of diphenoxylate HCl and 0.025 mg. of atropine sulfate per 5 ml. A plastic dropper calibrated in increments of ½ ml. (total capacity, 2 ml.) accompanies each 2-oz. bottle of Lomotil liquid.

SEARLE **Searle & Co.**
San Juan, Puerto Rico 00936

Address medical inquiries to:
G. D. Searle & Co.
Medical Department, Box 5110,
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IN ACUTE
OTITIS MEDIA

WHILE AN
ANTIBIOTIC
ATTACKS
THE PATHOGEN

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OTIC SOLUTION
PROMPTLY
RELIEVES THE
PAIN**

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Benzocaine	14.0 mg.
Glycerin dehydrated q.s. to	1.0 cc.

(contains not more than 0.6% moisture)
(Also contains oxyquinoline sulfate.)

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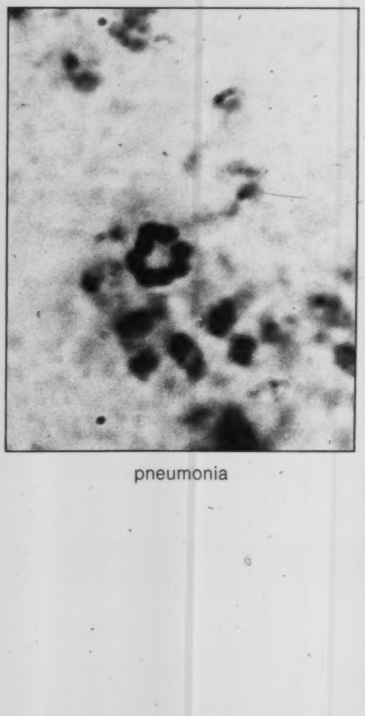
portohepatography



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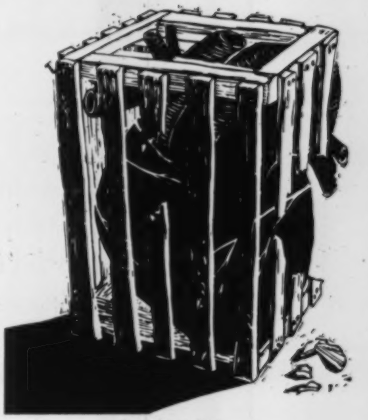

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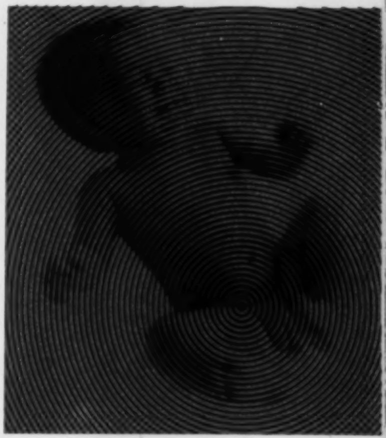
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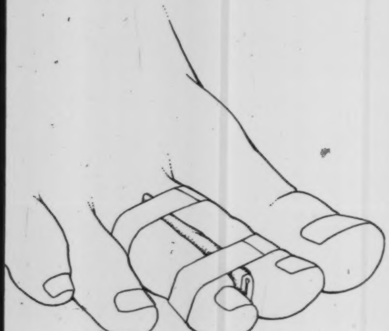
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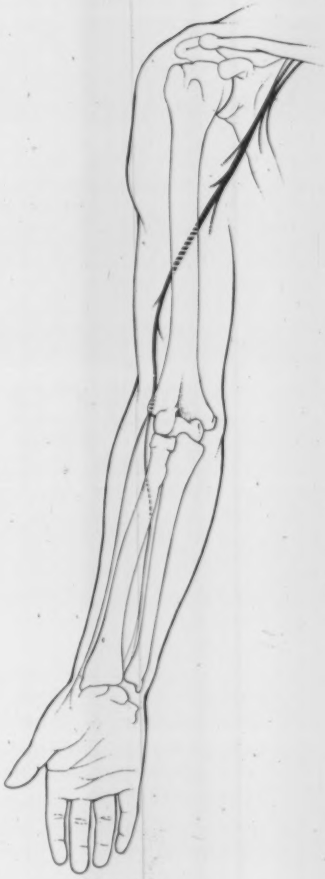

wrist drop

Before prescribing, please consult complete product information, a summary of which follows:

INDICATIONS: Tigan is indicated for the control of nausea and vomiting.

CONTRAINDICATIONS: The injectable form of Tigan in children, the suppositories in premature or newborn infants, and use in patients with known hypersensitivity to trimethobenzamide are contraindicated. Since the suppositories contain benzocaine they should not be used in patients known to be sensitive to this or similar local anesthetics.

WARNINGS: Tigan may produce drowsiness. Patients should not operate motor vehicles or other dangerous machinery until their individual responses have been determined. Reye's Syndrome has been associated with the use of Tigan and other drugs, including antiemetics, although their contribution, if any, to the cause and course of the disease hasn't been established. This syndrome is characterized by an abrupt onset shortly following a nonspecific febrile illness, with persistent severe vomiting, lethargy, irrational behavior, progressive encephalopathy leading to coma, convulsions and death.

Usage in Pregnancy: Trimethobenzamide hydrochloride was studied in reproduction experiments in rats and rabbits and no teratogenicity was suggested. The only effects observed were an increased percentage of embryonic resorptions or stillborn pups in rats administered 20 mg and 100 mg/kg and increased resorptions in rabbits receiving 100 mg/kg. In each study these adverse effects were attributed to one or two dams. The relevance to humans is not known. Since there is no adequate experience in pregnant or lactating women who have received this drug, safety in pregnancy or in nursing mothers has not been established.

PRECAUTIONS: During the course of acute febrile illness, encephalitides, gastroenteritis, dehydration and electrolyte imbalance, especially in children and the elderly or debilitated, CNS reactions such as opisthotonos, convulsions, coma and extrapyramidal symptoms have been reported with and without use of Tigan or other antiemetic agents. In such disorders caution should be exercised in administering Tigan, particularly to patients who have recently received other CNS-acting agents (phenothiazines, barbiturates, belladonna derivatives). It is recommended that severe emesis should not be treated with an antiemetic drug alone; where possible the cause of vomiting should be established. Primary emphasis should be directed toward the restoration of body fluids and electrolyte balance, the relief of fever and relief of the causative disease process. Overhydration should be avoided since it may result in cerebral edema.

The antiemetic effects of Tigan may render diagnosis more difficult in such conditions as appendicitis and obscure signs of toxicity due to overdosage of other drugs.

ADVERSE REACTIONS: There have been reports of hypersensitivity reactions and Parkinson-like symptoms. There have been instances of hypotension reported following parenteral administration to surgical patients. There have been reports of blood dyscrasias, blurring of vision, coma, convulsions, depression of mood, diarrhea, disorientation, dizziness, drowsiness, headache, jaundice, muscle cramps and opisthotonos. If these occur, the administration of the drug should be discontinued. Allergic-type skin reactions have been observed; therefore, the drug should be discontinued at the first sign of sensitization. While these symptoms will usually disappear spontaneously, symptomatic treatment may be indicated in some cases.

HOW SUPPLIED: Capsules, 250 mg trimethobenzamide hydrochloride each, bottles of 100 and 500; 100 mg trimethobenzamide hydrochloride each, bottles of 100.

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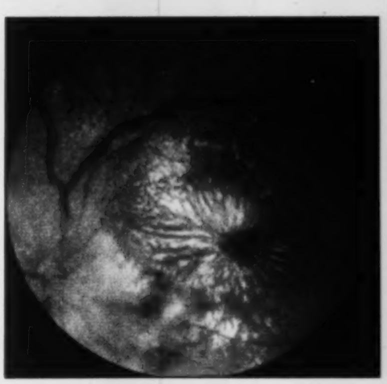

hypertension

back pain

Convenient therapy to lower the blood pressure and help keep it down in essential hypertensive patients

Aldactazide®

(spironolactone 25 mg./hydrochlorothiazide 25 mg.)

additive action for antihypertensive-diuretic-antialdosterone effect

Indications—Hypertension; edema of congestive heart failure, cirrhosis of the liver and the nephrotic syndrome; idiopathic edema. Some patients with malignant effusion may benefit from Aldactazide therapy.

Contraindications—Acute renal insufficiency, rapidly progressing impairment of the renal function. Anuria; sensitivity to thiazides or other sulfonamide-derived drugs. Probably contraindicated in acute or severe hepatic failure.

Warnings—Fixed-dose combination drugs are not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual patient. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. The treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Potassium supplementation is recommended only in exceptional instances, but may be considered when a glucocorticoid is also given. Utilize normal dietary sources of potassium if possible when potassium supplementation is necessary. If enteric-coated potassium is used be alert to the possible development of hemorrhagic, stenotic, ulcerated or perforated small-bowel lesions; deaths have occurred. The possibility of exacerbation or activation of systemic lupus erythematosus by sulfonamide derivatives, including thiazides, has been reported.

Administer thiazides with caution to pregnant or lactating patients. Adverse reactions which may occur in the adult (hyperbilirubinemia, thrombocytopenia, altered carbohydrate metabolism, etc.) may possibly occur in the newborn, since thiazides cross the placental barrier and may also appear in breast milk.

Precautions—Consider the possibility of fluid and electrolyte imbalance. Serum and urine electrolyte determinations are particularly important in patients with excessive vomiting or in those receiving fluids parenterally. Medications such as digitalis may also influence serum electrolytes. Warning signs of possible fluid and electrolyte imbalance are: dryness of the mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains, cramps or fatigue, hypotension, oliguria, tachycardia, gastrointestinal symptoms. Hypokalemia may develop with brisk diuresis in severe cirrhosis or during the concomitant use of glucocorticoids or ACTH. Inadequate oral electrolyte intake contributes to hypokalemia. Hypokalemia may cause signs of digitalis intoxication with previously tolerated doses of digitalis.

Give Aldactazide cautiously to patients with severe liver disease since thiazides can precipitate hepatic coma; discontinue if mental confusion increases. Consider also other factors that may precipitate hepatic coma, including blood in the gastrointestinal tract or preexistent potassium depletion. Reversible elevation of NPN and BUN may occur in some patients receiving Aldactazide. The most common electrolyte disturbance is dilutional hyponatremia which requires appropriate corrective measures. A true low-salt syndrome is rare; discontinue Aldactazide and administer sodium for this condition.

Although rare, the most potentially serious electrolyte disturbance is hyperkalemia; if this occurs discontinue Aldactazide and restrict potassium intake. Rarely, fatality due to hyperkalemia has been reported. Hyperkalemia is more likely to occur in severely ill patients with relatively small urine output or in patients receiving supplemental potassium; determine serum electrolytes frequently in such patients. Consider the possibility of hyperuricemia or a decrease in tolerance to glucose.

Patients with severely resistant edema may have an increased diuretic response following the addition of a potent glucocorticoid, such as 15 to 20 mg. of prednisone daily, to Aldactazide therapy. Supplemental potassium will usually be necessary in such patients and the usual precautions with glucocorticoids are necessary. Use caution if regional or general anesthesia is necessary since Aldactazide reduces vascular responsiveness to norepinephrine in such patients. Thiazides may increase responsiveness to tubocurarine. The antihypertensive effects of hydrochlorothiazide may be enhanced in patients who have undergone sympathectomy.

Pathologic changes in the parathyroid glands, with hypercalcemia and hypophosphatemia, have been observed in a few patients on prolonged thiazide therapy.

Thiazides may increase serum PBI levels without signs of thyroid disturbance.

Adverse Reactions reported with *spironolactone* use: Drowsiness and lethargy, mental confusion, diarrhea and other gastrointestinal symptoms, mild androgenic manifestations (including hirsutism, menstrual irregularity, deepening of the voice), gynecomastia, inability to achieve or to maintain erection, headache, maculopapular or erythematous cutaneous eruptions, urticaria, drug fever, ataxia.

Adverse Reactions reported with *thiazide* use: purpura, thrombocytopenia, leukopenia, agranulocytosis, gastrointestinal disorders (anorexia, nausea, vomiting, diarrhea, abdominal cramps), rash, pruritus, paresthesia, acute pancreatitis, jaundice, dizziness, vertigo, headache, xanthopsia, photosensitivity, urticaria, necrotizing angiitis, aplastic anemia, orthostatic hypotension, muscle spasm, weakness, restlessness. Reduce dosage or withdraw drug whenever adverse reactions are moderate or severe.

Dosage and Administration—Dosage should be determined by individual titration. *For essential hypertension* the daily *adult* dosage is two to four tablets in divided doses; continue treatment for two weeks or longer. Adjust the dosage according to the response of the patient. Reduce the dosage of other antihypertensive agents, particularly ganglionic blocking agents, by 50 percent since Aldactazide potentiates the action of such drugs. *For edema, ascites or effusion in adults* the average dosage is one tablet 4 times daily; dosage may range from 1 to 8 tablets daily in divided doses. The daily dosage of Aldactazide *in children* should provide 0.75 to 1.5 mg. of Aldactone® (spironolactone) per pound of body weight.

SEARLE **Searle & Co.**
San Juan, Puerto Rico 00936

Address medical inquiries to: G. D. Searle & Co.
Medical Department, Box 5110, Chicago, Ill. 60680 413R

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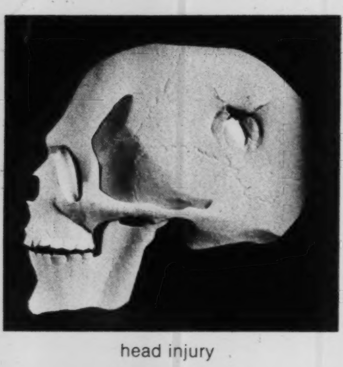

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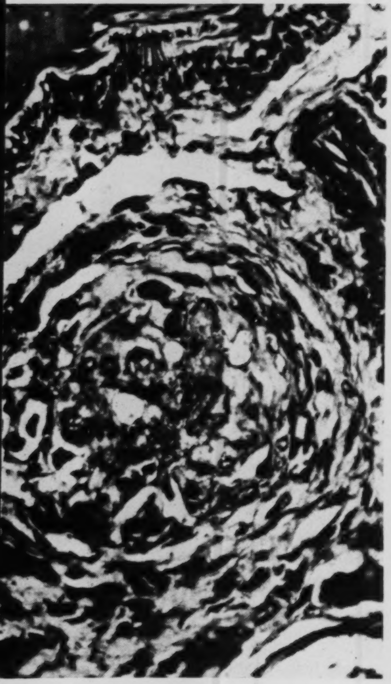

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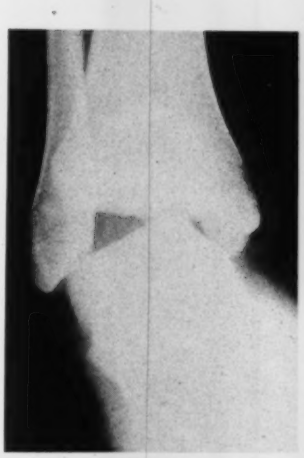

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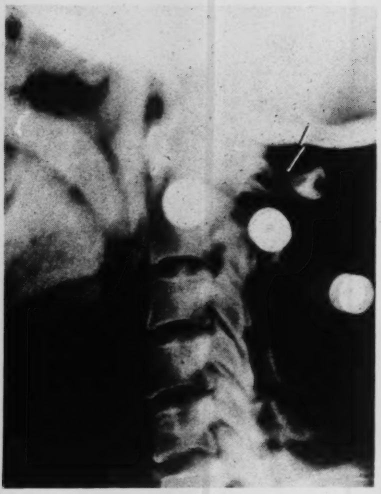

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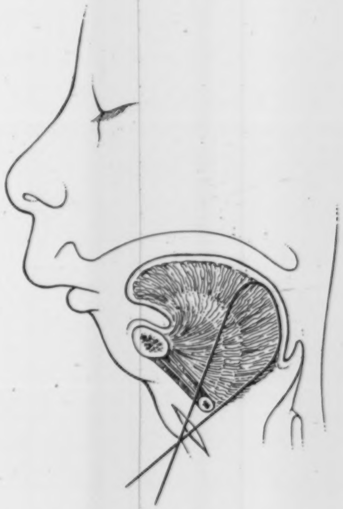

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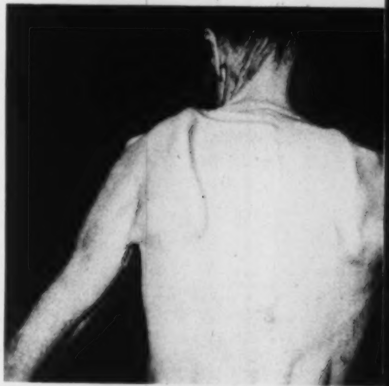

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